

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ENDO PHARMACEUTICALS INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.,

Defendant.

Case No. 13-cv-3288-TPG

**PUBLICLY FILED
REDACTED VERSION**

**ROXANE’S MEMORANDUM IN SUPPORT OF ITS MOTION
FOR LEAVE TO FILE A FIRST AMENDED ANSWER**

PRELIMINARY STATEMENT

Following a meet-and-confer, Endo Pharmaceuticals Inc. advised Roxane Laboratories, Inc. that it will not oppose Roxane’s amendment of its answer to add the twelfth affirmative defense of unclean hands, but opposes Roxane’s amendment adding the proposed tenth affirmative defense of express license and the proposed eleventh affirmative defense of implied license.

BACKGROUND

As the Court will recall, on May 15, 2013, Endo filed its complaint against Roxane for infringement of U.S. Patent Nos. 7,851,122; 8,329,216; and 7,851,482 (“‘122 patent, ‘216 patent, and ‘482 patent,” respectively). (D.I. 1.) Nearly three months later, Endo belatedly moved for a preliminary injunction against Roxane. At a status hearing on August 26, 2013, the Court suggested that, instead of submitting briefing on all the many issues implicated in Endo’s motion for preliminary injunction, the parties initially submit briefs confined solely to the issue of

whether the licenses Endo previously granted to Roxane pertaining to the same ANDA products at issue in this suit effectively dispose of Endo's latest infringement claims.

On September 12, 2013, the Court, having considered the parties' briefs and oral arguments, denied the preliminary injunction, holding as a matter of law that Endo was estopped from asserting the '122 and '216 patents against Roxane based on the earlier settled litigation. The Court did not reach or make any factual findings with respect to Roxane's express-license defense, nor did the Court reach any other of the many grounds why a preliminary injunction should not issue (unlikelihood of success on the merits, lack of irreparable harm, etc.).

Endo appealed the Court's denial of a preliminary injunction based on implied license. On March 31, 2014 the Federal Circuit vacated and remanded, holding on the preliminary-injunction record that Roxane did not have an implied license. The appeals court also reached out to an issue that this Court had neither considered nor decided and opined that Roxane did not have an express license. Roxane filed a petition for rehearing en banc seeking further review of the only issue properly before the Federal Circuit, namely, the implied-license issue. The Federal Circuit denied rehearing on June 3, 2014.

While the preliminary injunction was on appeal, and in furtherance of its license defenses, Roxane deposed Guy Donatiello, Endo's in-house counsel, who had submitted the declaration that Endo filed in connection with the preliminary-injunction proceedings. Also, Endo deposed Donatiello's counterpart at Roxane, David Dow, who was Roxane's principal negotiator of the license that Endo granted to Roxane in settlement of the previous patent litigation involving Roxane's same ANDA product at issue here. Both of these depositions focused in large part on the parties' negotiations and understanding of the terms in that earlier settlement and license agreement. Roxane and Endo also both produced their written

communications reflecting the negotiations and the parties' intent leading up to their entering the license agreement. Of course, neither of these depositions and none of these written communications were before this Court, or before the Federal Circuit, in connection with the preliminary-injunction ruling or its review.

At the same time, Roxane continued to take discovery on other issues in the case. One other aspect of the discovery centered on circumstances regarding the supply agreement between Roxane and Johnson Matthey (for supply of the active oxymorphone hydrochloride ingredient in Roxane's formulation) [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Roxane explored those issues with Endo's Donatiello at his deposition and has served a subpoena on Johnson Matthey. Johnson Matthey has moved to quash that subpoena, a motion that is fully briefed and currently pending before this Court.

Roxane now seeks leave to amend its answer in this case and assert three defenses not before pled but that have already been the focus of discovery: express license to practice the '122 and '216 patents; implied license to practice the '122 and '216 patents; and unclean hands. (Exhibits 1, 2¹.)

ARGUMENT

Roxane's proposed amended answer easily satisfies the liberal standards under the federal rules for leave to amend a pleading. Roxane's motion is timely as it is based on information recently revealed during fact discovery, which is still ongoing. Further, these

¹ "Exhibit __" refers to the corresponding exhibits to the Declaration of Myoka K. Goodin in Support of Roxane's Motion for Leave to File a First Amended Answer.

additional defenses will not cause undue prejudice because they will not cause delay or alter the nature of the litigation in any significant way.

I. Justice requires that the Court grant leave to amend the answer to assert the additional defenses of implied license, express license, and unclean hands.

The Supreme Court has commanded that district courts freely grant leave to amend a pleading when justice requires. Fed. R. Civ. P. 15(a); *Foman v. Davis*, 371 U.S. 178, 182 (1962); *United States ex rel. Maritime Admin. v. Continental Illinois Nat'l Bank & Trust Co.*, 889 F.2d 1248, 1254 (2d Cir. 1989) (applying the liberal Rule 15(a) standard and finding it improper to not allow an amendment); *Monahan v. New York City Dep't of Corr.*, 214 F.3d 275, 283 (2d Cir. 2000) (noting that “mere technicalities should not prevent cases from being decided on the merits”). Leave should ordinarily be granted unless the amendment (1) has been delayed unduly, (2) is sought for dilatory purposes or is made in bad faith, (3) the opposing party would be prejudiced, or (4) would be futile. *State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981) (citing *Foman*, 371 U.S. at 182); *Hinds County v. Wachovia Bank N.A.*, 291 F.R.D. 73, 74 (S.D.N.Y. 2013) (granting motion for leave to file amended complaint after finding no undue delay, dilatory practices, prejudice, or futility); *It's a 10, Inc. v. pH Beauty Labs, Inc.*, 718 F. Supp. 2d 332, 339-40 (S.D.N.Y. 2010). Mere delay, absent bad faith or prejudice, generally is not a valid reason for denying a motion to amend. *Duling v. Gristede's Operating Corp.*, 265 F.R.D. 91, 97, 98-99 (S.D.N.Y. 2010) (absent prejudice, no abuse of discretion to permit amendment of answer to assert additional affirmative defense after a seven-year delay); *ResQNet.com, Inc. v. Lansa, Inc.*, 382 F. Supp. 2d 424, 449-51 (S.D.N.Y. 2005) (“Mere delay provides an insufficient basis to deny a motion to amend absent a showing of bad faith or undue prejudice.”); *Rotter v. Leahy*, 93 F. Supp. 2d 487, 499 (S.D.N.Y. 2000) (amendment granted where no prejudice found). Moreover, Endo has the burden to demonstrate

any purported bad faith or undue prejudice that it would contend would result from the amendments. *Block v. First Blood Associates*, 763 F. Supp. 746, 748 (S.D.N.Y. 1991) *aff'd*, 988 F.2d 344 (2d Cir. 1993)(“a party opposing a proposed amendment on the basis of delay must also demonstrate either the amending party’s bad faith or the undue prejudice which would result from the amendment”); *Panzella v. Skou*, 471 F. Supp. 303, 305 (S.D.N.Y. 1979)(“Since plaintiff has failed to demonstrate that prejudice would result from such amendment, defendant’s motion to amend its answer to assert the affirmative defense...is granted.”). Here, justice requires the amendment that Roxane seeks, and none of the above negative factors are present.

A. Roxane has not unduly delayed in seeking leave to amend, nor is Roxane proceeding in bad faith.

Endo’s consent to add one new defense (unclean hands) appears to confirm that there has been no undue delay or bad faith here in general. The facts would not support a finding of undue delay or bad faith in any event.

First we address delay. Unlike this Court, which did not credit evidence of the parties’ settlement negotiations in deciding the issue of legal estoppel and implied license, the Federal Circuit’s opinion (we think wrongly) did appear to credit that evidence, albeit only Endo’s version of it. That opinion issued on March 31, 2014.. Moreover, the depositions of Donatiello and Dow, which supplied more detail on this issue, were just completed in March of this year.

Further, fact discovery is ongoing, with no cut-off date yet imposed. Endo, itself, less than a week before the filing of this motion, served another Rule 30(b)(6) notice on Roxane. So, too, substantial discovery has already focused on the license issues. Thus, amendment also will not unduly delay the progress of this litigation. *Fustok v. Conticommodity Services, Inc.*, 103 F.R.D. 601, 603-04 (S.D.N.Y. 1984) (finding that the fact that there has already been much discovery in this case does not, alone, prevent a party from amending pleadings); *Rivera v. Dyett*,

No. 88 Civ 4707, 1993 WL 54652, at *5 (S.D.N.Y. Feb. 16, 1993) (granting leave to amend even though it “may place a burden on the defendants by requiring them to engage in additional discovery.”)

Bad faith is also not an issue here. Roxane is not seeking to amend its answer frivolously or for some ulterior purpose such as delay. *Am. Med. Ass’n v. United Healthcare Corp.*, No. 00 Civ 2800, 2006 WL 3833440, at *5 (S.D.N.Y. Dec. 29, 2006) (granting leave to amend where movant did not have ulterior motives such as delay). Further, the parties briefed the license issues at the preliminary-injunction stage and on appeal, and have continued to conduct discovery directed to these defenses, so there can be no claim of surprise in any event.

B. Amendment will not unduly prejudice Endo

In ascertaining whether the nonmoving party will sustain undue prejudice, courts in this circuit consider whether the assertion of the new defense would: “(i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction.” *Block v. First Blood Associates*, 988 F.2d 344, 350 (2d Cir. 1993); *Monahan*, 214 F.3d at 284 (“the fact that one party has spent time and money preparing for trial will usually not be deemed prejudice sufficient to warrant a deviation from the rule broadly allowing amendment to pleadings”).

None of these issues is present here. The parties have already conducted substantial discovery on the license defenses, both express and implied, with respect to the ‘122 and ‘216 patents, even though these defenses were not initially specifically pled. Thus, allowance of these defenses would not require Endo to expend significant additional resources. Indeed, at present Roxane does not contemplate any further discovery needed on the license issues beyond what has already taken place. Regardless, since fact discovery has not yet closed, the assertion of

these defenses will not significantly delay resolution of the lawsuit. Nor is there any issue of precluding Endo from bringing a timely action elsewhere.

C. Amendment would be anything but futile.

Finally, Roxane's proposed amendments are far from futile. In determining whether an amendment would be futile, the Court should apply the familiar Rule 12(b)(6) standard and inquire whether the movant has pleaded such facts that would state a defense that is plausible on its face. *See Ricciuti v. N.Y.C. Transit Auth.*, 941 F.2d 119, 123 (2d Cir. 1991) (determinations of futility are made under the same standards that govern Rule 12(b)(6) motions to dismiss). In other words, there must be sufficient factual allegations to show more than a mere possibility that the defense applies. *See Inside Radio v. Clear Channel Communs.*, 209 F. Supp. 2d 302, 307 (S.D.N.Y. 2002) *quoting Conley v. Gibson*, 355 U.S. 41, 45-46 (1957) (The court "should not preclude the addition of the proposed claim on the ground of futility 'unless it appears beyond doubt that the [party] can prove no set of facts in support of his claim which would entitle him to relief.'")

Here, Roxane has sufficiently alleged three defenses that are plausible on their face: express license; implied license; and unclean hands. But before we address each specific defense, we turn to a threshold issue involving the effect of the Federal Circuit's recent ruling, which applies only to the express- and implied-license defenses, and not to the unclean-hands defense.

1. The Federal Circuit's ruling on the preliminary injunction does not preclude these new defenses

Endo should not be heard to argue that the Federal Circuit's recent decision bars Roxane from asserting the defenses of express license and implied license. The United States Supreme Court has recognized that the purpose of a preliminary injunction is limited: to preserve the

parties' positions until the court can hold a trial on the merits. *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). Thus, as occurred here, a preliminary injunction is usually decided on procedures less formal and evidence less complete than a trial on the merits. *Id.* For these reasons, longstanding precedent holds that findings of fact and conclusions of law made on a motion for preliminary injunction are not binding at trial on the merits. *Id.*; *see also Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 681 (Fed. Cir. 1990) (“[T]he issue is whether the district court abused its discretion in granting or denying a motion for a preliminary injunction after a hearing in which neither party was required to prove his case in full and in light of findings and conclusions not binding at trial....This is only the first round, involving only a preliminary injunction, a matter of equity....”) (emphasis in original). Further, the Federal Circuit has unequivocally held that its own opinion on review of a preliminary injunction “has no conclusive bearing at the trial on the merits and is not binding on a subsequent panel.” *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1346 (Fed. Cir. 2004). Accordingly, the Federal Circuit’s ruling on the preliminary-injunction appeal does not preclude the parties from developing further evidence, as Roxane has done here, to support theories that the appellate court rejected preliminarily in its March 31, 2004 opinion.

2. Roxane’s amendments sufficiently allege the three defenses at issue here

Roxane’s proposed answer more than adequately alleges facts to show more than a mere possibility that these three defenses apply. Accordingly, amendment is not futile.

a. Express license.

Roxane has sufficiently pled, in its amended answer, a defense of express license that is plausible on its face. Specifically, the amended answer alleges that:

- On November 9, 2009, Roxane filed ANDA No. 20-0822 seeking FDA approval to manufacture and sell a generic alternative to Endo's 40 mg strength of original formulation Opana® ER. (Recall that Endo has two formulations of Opana ER: (1) the original formulation (NDA No. 021610) for which Roxane is seeking approval; and (2) a so-called crush resistant formulation (NDA No. 201655).)
- On March 10, 2010, Roxane supplemented its ANDA seeking FDA approval to manufacture and sell generic alternatives to Endo's 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths of original formulation Opana® ER.
- At the time Roxane filed its ANDA, Endo had three patents, including U.S. Patent No. 7,276,250 ("250 patent"), listed in FDA's Orange Book as covering the original formulation of Opana® ER.
- Under 21 U.S.C. § 355(j)(2)(A)(iv) Roxane's ANDA contained Paragraph IV certifications with respect to all three of Endo's Orange Book listed patents.
- Endo filed suit against Roxane alleging infringement of U.S. Patent No. 5,958,456 ("456 patent") under the Hatch-Waxman Act, but Endo provided a covenant not to sue Roxane with respect to two of the Orange Book-listed patents for NDA No. 0210610, U.S. Patent No. 5,662,933 ("the '933 patent") and the '250 patent.
- After incurring substantial litigation costs, Endo and Roxane entered into the 2011 Settlement and License Agreement.
- Under the terms of the settlement and license agreement, and in exchange for valuable consideration, Endo granted Roxane "a non-exclusive, non-transferable..., non-sublicensable and royalty-free license..., under the Licensed Patents, during the License

Term, to make, use, have made, sell, offer to sell, import and use the Roxane Products solely in the Territory.”

- The settlement and license agreement defined the “License Term” as “commenc[ing] on the applicable Commencement Date for each Roxane Product and will continue, unless earlier suspended or terminated pursuant to this Agreement, until the expiration or abandonment of all claims of the Licensed Patents.”
- The settlement and license agreement also defined the “Licensed Patents” as “any United States patents that are both (i) now owned by Endo, Penwest and/or any of their Affiliates, and (ii) issued as of the Effective Date of this Agreement, including the Opana® ER Patents, (b) any United States patent applications that claim priority to the Opana® ER Patents, including any continuation, continuation-in-part and divisional patent applications that claim priority to the Opana® ER Patents, and (c) any patents resulting from the reissue or reexamination of patents or patent applications comprised within clauses (a) and (b) above, in each case that Endo and/or Penwest could assert would be infringed by the making, using, selling, offering to sell or importing of the Roxane Product.”
- The settlement and license agreement defined the “Opana ER Patents” as “U.S. Patent Nos. 5,662,933, 5,958,456 and 7,276,250, and any U.S. patents resulting from any reissue or reexamination thereof.”
- In addition, in accordance with the settlement and license agreement, Endo covenanted not to sue Roxane for infringement of the “Licensed Patents”: “Endo and Penwest, on behalf of itself and its Affiliates and its officers and directors, covenant that they will not sue, assert any claim or counterclaim against, or otherwise participate in any action or

proceeding against Roxane or their permitted successors and assigns or any of Roxane's suppliers, distributors, wholesalers or customers (collectively the "Roxane Parties"), or cause or authorize any person or entity to do any of the foregoing, in each case claiming or otherwise asserting that the manufacture, use, sale, offer for sale or distribution of Roxane Products under the Roxane ANDA in the Territory on or after the applicable Commencement Date (subject to Roxane's permitted pre-Commencement Date activities set forth in Section 3.2) by Roxane, infringes the Licensed Patents, so long as Roxane is in compliance with the terms of this Agreement (the "Covenant Not to Sue")."

- Endo subsequently obtained additional patents, the '122 and the '216 patent.
- Endo filed this new lawsuit alleging infringement of the claims of these new patents by Roxane.
- The '122 and '216 patents both claim priority to U.S. Provisional Patent Application No. 60/303,357 ("357 application"), to which the '250 patent also claims priority.
- Because the '122 patent, the '216 patent, and the '250 patent all claim priority to the '357 application, the settlement and license agreement is applicable to the '122 and '216 patents, giving Roxane an express license to practice the claims of the '122 and '216 patents.
- To the extent the settlement and license agreement is deemed ambiguous, parol evidence establishes that the parties intended it to cover any and all future Endo patents that would purportedly cover the original formulation Opana[®] ER.

Further, if the settlement and license agreement is deemed ambiguous, Roxane has adduced evidence that Roxane intended to secure, and believed it had secured, an express license to practice the subject matter claimed in the '122 and '216 patents for purposes of bringing its

ANDA product on the original Opana ER formulation to market. While a discussion of this evidence is premature in this motion for leave to amend, Roxane merely wishes to highlight that the negotiation history recited in Endo's papers leading up to the preliminary injunction was one-sided (Roxane did not have a chance to respond to Endo's evidence or introduce its own evidence of the negotiations due to the abbreviated briefing schedule) and incomplete, in line with the preliminary nature of the remedy Endo sought.

3. **Implied License**

Similarly, Roxane has sufficiently pled, in its amended answer, a defense of implied license that is plausible on its face. Specifically, the amended answer alleges that:

- On November 9, 2009, Roxane filed ANDA No. 20-0822 seeking FDA approval to manufacture and sell a generic alternative to Endo's original formulation of Opana® ER under NDA No. 021610.
- On March 10, 2010, Roxane supplemented its ANDA seeking FDA approval to manufacture and sell generic alternatives to Endo's 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths of original formulation Opana® ER.
- At the time Roxane filed its ANDA, Endo had three patents listed in FDA's Orange Book as covering the original formulation of Opana® ER.
- Under 21 U.S.C. § 355(j)(2)(A)(iv), Roxane's ANDA contained Paragraph IV certifications with respect to all three of Endo's Orange Book-listed patents.
- Endo filed suit against Roxane alleging infringement of the '456 patent, under the Hatch-Waxman Act, but Endo agreed to a covenant not to sue Roxane with respect to two of the Orange Book-listed patents for NDA No. 021610, the '933 patent and the '250 patent.

- After incurring substantial litigation costs, Endo and Roxane entered into the 2011 Settlement and License Agreement.
- Under the terms of the settlement and license agreement, Endo provided Roxane a patent license and covenant not to sue to Roxane regarding the product that was the subject of Roxane's ANDA.
- Endo, however, subsequently obtained additional patents, the '122 patent and the '216 patent, purportedly covering Roxane's same ANDA product and filed this infringement lawsuit against Roxane alleging infringement of the same Roxane ANDA product that Endo provided a patent license and covenant not to sue in the settlement and license agreement.
- Roxane reasonably relied on the terms of the settlement and license agreement and proceeded with preparations to obtain FDA approval and market its ANDA product.
- By this lawsuit, Endo seeks to derogate from the rights it granted Roxane for good consideration in the settlement and license agreement to end the previous lawsuit involving the same Roxane ANDA product.
- Endo is legally estopped from asserting infringement claims that would preclude Roxane from making, using, and selling the same ANDA product at issue in the earlier litigation.

These allegations track the requirements for legal estoppel/implied license set forth in *TransCore, LP v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009), *Gen. Protecht Grp., Inc. v. Leviton Mfg. Co.*, 651 F.3d 1355 (Fed. Cir. 2011), and *AMP, Inc. v. U.S.*, 389 F.2d 448 (Ct. Cl. 1968). They more than sufficiently allege a defense of implied license that is plausible on its face.

4. **Unclean Hands**

Endo agreed during the meet-and-confer for this motion that Roxane should be allowed to amend its answer to assert this defense. This defense arises out of Endo's post-settlement conduct in dealing with Roxane's supplier and its institution and conduct of this lawsuit.

The guiding doctrine in this case is the equitable maxim that 'he who comes into equity must come with clean hands.' This maxim is far more than a mere banality. It is a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant. That doctrine is rooted in the historical concept of court of equity as a vehicle for affirmatively enforcing the requirements of conscience and good faith. This presupposes a refusal on its part to be 'the abetter of iniquity.'

Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 814 (1945) (quoting *Bein v. Heath*, 47 U.S. 228, 247 (1848)).

The defense of unclean hands is a mainstay of equity jurisprudence, and applies in patent cases no differently than in other contexts. The doctrine is not statutorily based, or even dependent on precedent, but rather is founded on basic principles of fairness and justice:

'It is one of the fundamental principles upon which equity jurisprudence is founded, that before a complainant can had a standing in court he must first show that not only has he a good and meritorious cause of action, but he must come into court with clean hands. He must be frank and fair with the court, nothing about the case under consideration should be guarded, but everything that tends to a full and fair determination of the matters in controversy should be placed before the court.' Story's Equity Jurisprudence (14th ed.) § 98.

Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 244-45 (1933).

Roxane's proposed amended answer alleges a multitude of facts to support an unclean-hands defense:

- Endo has engaged in conduct during its negotiations with Roxane and the pendency of this litigation that, considered separately or together, constitutes unclean hands. As a result, Endo should be precluded from any recovery in this suit.

- Upon information and belief, Endo filed this lawsuit asserting the ‘482 patent against Roxane with knowledge that Roxane has a license, arising out of its supply agreement with Johnson Matthey, the former owner of the ‘482 patent, to purchase and sell the active pharmaceutical ingredient in Roxane’s generic version of the original formulation Opana® ER.
- Upon information and belief, before Endo purchased the ‘482 patent from Johnson Matthey, [REDACTED]
[REDACTED]
[REDACTED].
- [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- [REDACTED]
[REDACTED]
[REDACTED]
- These actions by Endo are part of an improper effort to keep Roxane from entering the generic oxymorphone hydrochloride market through means beyond the legitimate rights that Endo owns under the patents.

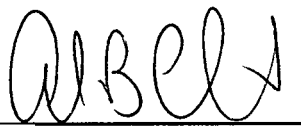
- By filing and maintaining this lawsuit in light of these actions, Endo is not coming to this Court with clean hands and therefore deserves no remedy from this Court.

Further, Roxane expects to glean additional facts from Johnson Matthey to support its unclean-hands defense once there is resolution of Johnson Matthey's motion to quash the subpoenas Roxane served on it.

CONCLUSION

For these reasons, the Court should grant Roxane leave to amend its answer to assert these additional affirmative defenses.

Dated: June 23, 2014

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